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PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (formerly known as "Monsanto Company"¹) ("Pharmacia"), and G.D. Searle LLC ("Searle") (collectively "Defendants"), and file this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

8 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
9 Bextra® (valdecoxib) (“Bextra®”). Accordingly, this Answer can only be drafted generally.
10 Defendants may seek leave to amend this Answer when discovery reveals the specific time
11 periods in which Plaintiff was prescribed and used Bextra®.

II.

ANSWER

Response to Allegations Regarding Parties

- 15 1. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and
17 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this
18 paragraph of the Complaint.

19 2. Defendants admit that Pfizer is a Delaware corporation with its principal place of
20 business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
21 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
22 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
23 Bextra® in the United States to be prescribed by healthcare providers who are by law

¹ Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Bextra®. Given that Plaintiff alleges in the Complaint that Monsanto Company was involved in distributing Bextra®, see PLAINTIFF'S COMPLAINT at ¶ 5, Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

1 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
2 that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.
3 Defendants are without knowledge or information to form a belief as to the truth of such
4 allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this
5 paragraph of the Complaint.

6 3. Defendants admit that Searle is a Delaware limited liability company with its principal
7 place of business in Illinois. Defendants admit that, during certain periods of time, Bextra®
8 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
9 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
10 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
11 deny the remaining allegations in this paragraph of the Complaint.

12 4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
13 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia
14 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
15 providers who are by law authorized to prescribe drugs in accordance with their approval by the
16 FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are
17 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
18 the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining
19 allegations in this Paragraph of the Complaint.

20 5. Defendants admit that in 1933 an entity known as Monsanto Company ("1933
21 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of
22 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name
23 to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company,
24 was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company
25 changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged
26 in the agricultural business and does not and has not ever manufactured, marketed, sold, or
27 distributed Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle
28 or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold,

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1 or distributed Bextra®, Defendants therefore state that the 2000 Monsanto is not a proper party
2 in this matter. Defendants deny the remaining allegations in this paragraph of the Complaint.
3 Defendants state that the response to this paragraph of the Complaint regarding Monsanto is
4 incorporated by reference into Defendants' responses to each and every paragraph of the
5 Complaint referring to Monsanto and/or Defendants.

6 6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
7 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
8 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
9 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
10 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
11 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
12 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Bextra® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
17 remaining allegations in this paragraph of the Complaint.

18 7. Defendants state that the allegations in this paragraph of the Complaint regarding
19 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
20 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
21 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 **Response to Allegations Regarding Jurisdiction and Venue**

23 8. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and
25 the amount in controversy, and, therefore, deny the same. However, Defendants admit that
26 Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000,
27 exclusive of interests and costs.

28 9. Defendants are without knowledge or information sufficient to form a belief as to the

1 truth of the allegations in this paragraph of the Complaint regarding the judicial district in
2 which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny
3 committing a tort in the State of Michigan or the State of California and deny the remaining
4 allegations in this paragraph of the Complaint.

5 10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
6 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
7 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
8 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
9 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
10 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
11 accordance with their approval by the FDA. Defendants admit that they provided FDA-
12 approved prescribing information regarding Bextra®. Defendants admit that they do business
13 in the State of California. Defendants state that Plaintiff's allegations regarding "predecessors
14 in interest" are vague and ambiguous. Defendants are without knowledge or information to
15 form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny
16 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

17 **Response to Allegations Regarding Interdistrict Assignment**

18 11. Defendants state that this paragraph of the Complaint contains legal contentions to
19 which no response is required. To the extent that a response is deemed required, Defendants
20 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
21 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
22 Panel on Multidistrict Litigation on September 6, 2005.

23 **Response to Factual Allegations**

24 12. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
26 condition and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny
27 the remaining allegations this paragraph of the Complaint.

28 13. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
2 condition and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny
3 that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this
4 paragraph of the Complaint.

5 14. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
7 condition and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny
8 any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the
9 remaining allegations in this paragraph of the Complaint.

10 15. Defendants admit that Bextra® was expected to reach consumers without substantial
11 change from the time of sale. Defendants are without knowledge or information sufficient to
12 form a belief as to the truth of the allegations in this paragraph of the Complaint regarding
13 whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny the remaining
14 allegations this paragraph of the Complaint.

15 16. Defendants state that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants are without knowledge or information sufficient to form a belief as to the truth of
20 the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
21 and, therefore, deny the same. Defendants deny remaining the allegations in this paragraph of
22 the Complaint.

23 17. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-
24 steroidal anti-inflammatory drugs ("NSAIDS"). Defendants state that Bextra® was and is safe
25 and effective when used in accordance with its FDA-approved prescribing information.
26 Defendants state that the potential effects of Bextra® were and are adequately described in its
27 FDA-approved prescribing information, which was at all times adequate and comported with
28 applicable standards of care and law. Defendants deny the remaining allegations in this

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1 paragraph of the Complaint.

2 18. The allegations in this paragraph of the Complaint are not directed toward Defendants
3 and, therefore, no response is required. To the extent a response is deemed required,
4 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
5 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
6 form a belief as to the truth of such allegations and, therefore, deny the same.

7 19. The allegations in this paragraph of the Complaint are not directed toward Defendants
8 and, therefore, no response is required. To the extent a response is deemed required,
9 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
10 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
11 form a belief as to the truth of such allegations and, therefore, deny the same.

12 20. The allegations in this paragraph of the Complaint are not directed toward Defendants
13 and, therefore, no response is required. To the extent a response is deemed required,
14 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
15 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
16 form a belief as to the truth of such allegations and, therefore, deny the same.

17 21. The allegations in this paragraph of the Complaint are not directed toward Defendants
18 and, therefore, no response is required. To the extent a response is deemed required,
19 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
20 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
21 form a belief as to the truth of such allegations and, therefore, deny the same.

22 22. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
23 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth
24 of such allegations and, therefore, deny the same.

25 23. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are
26 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
27 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful
28 conduct and deny the remaining allegations in this paragraph of the Complaint.

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1 24. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless,
2 Defendants admit that Celebrex® was launched in the United States in February 1999.
3 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
4 FDA-approved prescribing information. Defendants admit that, during certain periods of time,
5 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
6 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
7 with their approval by the FDA. Defendants admit that, during certain periods of time,
8 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
9 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
10 providers who are by law authorized to prescribe drugs in accordance with their approval by the
11 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not
12 directed toward Defendants and, therefore, no response is required. To the extent a response is
13 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
14 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants
15 therefore lack sufficient information or knowledge to form a belief as to the truth of such
16 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this
17 paragraph of the Complaint.

18 25. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
19 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the
20 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
21 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.
22 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
23 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
24 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
25 this paragraph of the Complaint.

26 26. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.
27 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
28 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid

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1 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
2 allegations in this paragraph of the Complaint.

3 27. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
4 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
5 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
6 the remaining allegations in this paragraph of the Complaint.

7 28. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
8 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
9 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
10 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
11 prescribing information. Defendants state that the potential effects of Bextra® were and are
12 adequately described in its FDA-approved prescribing information, which at all times was
13 adequate and comported with applicable standards of care and law. Defendants deny the
14 remaining allegations in this paragraph of the Complaint.

15 29. Defendants state that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which at all times was adequate and comported with applicable standards of care and law.
19 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
20 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
22 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
23 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
24 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
25 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding
26 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
27 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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1 the Complaint.

2 30. Defendants state that the referenced article speaks for itself and respectfully refer the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Defendants state that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
6 this paragraph of the Complaint.

7 31. The allegations in this paragraph of the Complaint are not directed towards Defendants
8 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
9 state that the referenced article speaks for itself and respectfully refer the Court to the article for
10 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
11 the remaining allegations in this paragraph of the Complaint.

12 32. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
13 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November
14 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this
15 paragraph of the Complaint.

16 33. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which at all times was adequate and comported with applicable standards of care and law.
20 Defendants deny the allegations in this paragraph of the Complaint.

21 34. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and
22 respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to
23 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this
24 paragraph of the Complaint.

25 35. Defendants state that the referenced article speaks for itself and respectfully refer the
26 Court to the article for its actual language and text. Any attempt to characterize the article is
27 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

28 36. Plaintiff fails to provide the proper context for the allegations concerning the "post-drug

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1 approval meta-analysis study" in this paragraph of the Complaint. Defendants are without
2 sufficient information to confirm or deny such allegations and, therefore, deny the same.
3 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
4 the study for its actual language and text. Any attempt to characterize the study is denied.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 37. The allegations in this paragraph of the Complaint are not directed towards Defendants
7 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
8 state that the referenced article speaks for itself and respectfully refer the Court to the article for
9 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
10 the remaining allegations in this paragraph of the Complaint.

11 38. The allegations in this paragraph of the Complaint are not directed towards Defendants
12 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
13 admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk
14 Management Advisory Committee was held on February 16-18, 2005. Defendants state that the
15 referenced testimony speaks for itself and respectfully refer the Court to the testimony for its
16 actual language and text. Any attempt to characterize the testimony is denied. Defendants
17 deny the remaining allegations in this paragraph of the Complaint.

18 39. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
20 deny the remaining allegations in this paragraph of the Complaint.

21 40. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
22 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
23 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 41. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
26 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
27 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 42. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants deny the allegations in this
3 paragraph of the Complaint.

4 43. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
7 paragraph of the Complaint.

8 44. The allegations in this paragraph of the Complaint are not directed towards Defendants
9 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
10 state that the referenced article speaks for itself and respectfully refer the Court to the article for
11 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
12 the remaining allegations in this paragraph of the Complaint.

13 45. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny the allegations in this paragraph of the Complaint.

18 46. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
23 allegations in this paragraph of the Complaint.

24 47. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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1 the Complaint.

2 48. Defendants deny the allegations in this paragraph of the Complaint.

3 49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
4 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
5 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
6 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
7 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
8 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
9 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Bextra® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants are without knowledge or information
14 sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint
15 regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any
16 wrongful conduct and deny the allegations in this paragraph of the Complaint.

17 50. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
18 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
19 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
20 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
21 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
22 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
23 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Bextra® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny the remaining allegations in this
28 paragraph of the Complaint.

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1 51. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
2 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
3 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
4 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
5 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
6 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
7 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Bextra® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants admit, as indicated in the package insert
12 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
13 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
14 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 52. Defendants state that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which at all times was adequate and comported with applicable standards of care and law.
19 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
20 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
21 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
22 that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

23 53. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
24 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
25 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
26 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
27 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
28 be prescribed by healthcare providers who are by law authorized to prescribe drugs in

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1 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Bextra® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 54. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which at all times was adequate and comported with applicable standards of care and law.
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 55. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 56. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 57. Defendants deny the allegations in this paragraph of the Complaint.

25 58. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market
26 as of April 7, 2005. Defendants deny any wrongful conduct and deny the remaining allegations
27 contained in this paragraph of the Complaint.

28 59. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
5 allegations in this paragraph of the Complaint.

6 60. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 61. Defendants deny any wrongful conduct and deny the remaining allegations in this
13 paragraph of the Complaint.

14 62. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
19 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
20 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
21 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
22 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
23 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
24 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
25 remaining allegations in this paragraph of the Complaint.

26 63. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
27 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
28 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants

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1 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
2 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
3 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
4 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
5 paragraph of the Complaint.

6 64. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
7 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
8 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
9 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
10 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
11 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
12 accordance with their approval by the FDA. Defendants admit, as indicated in the package
13 insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and
14 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of
15 primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining
16 allegations in this paragraph of the Complaint.

17 65. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants are without knowledge or information sufficient to form a belief as to the truth of
22 the allegations in this paragraph of the Complaint regarding and whether Plaintiff used
23 Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
24 Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the
25 remaining allegations in this paragraph of the Complaint.

26 66. Defendants state that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants are without knowledge or information sufficient to form a belief as to the truth of
3 the allegations in this paragraph of the Complaint regarding and whether Plaintiff used
4 Bextra®, and, therefore, deny the same. Defendants state that Plaintiff's allegations regarding
5 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
6 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
7 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
8 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
9 Complaint.

10 **Response to First Cause of Action: Negligence**

11 67. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
12 Complaint as if fully set forth herein.

13 68. Defendants state that this paragraph of the Complaint contains legal contentions to
14 which no response is deemed required. To the extent a response is deemed required,
15 Defendants admit that they had duties as are imposed by law but deny having breached such
16 duties. Defendants state that the potential effects of Bextra® were and are adequately described
17 in its FDA-approved prescribing information, which was at all times adequate and comported
18 with applicable standards of care and law. Defendants state that Bextra® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 deny the remaining allegations in this paragraph of the Complaint.

21 69. Defendants state that this paragraph of the Complaint contains legal contentions to
22 which no response is deemed required. To the extent a response is deemed required,
23 Defendants admit that they had duties as are imposed by law but deny having breached such
24 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
26 this paragraph of the Complaint.

27 70. Defendants state that this paragraph of the Complaint contains legal contentions to
28 which no response is required. To the extent that a response is deemed required, Defendants

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1 admit that they had duties as are imposed by law but deny having breached such duties.
2 Defendants state that Bextra® was and is safe and effective when used in accordance with its
3 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
4 were and are adequately described in its FDA-approved prescribing information, which was at
5 all times adequate and comported with applicable standards of care and law. Defendants deny
6 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,
7 including all subparts.

8 71. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants are without knowledge or information sufficient to form a belief as to the truth of
13 the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
14 and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining
15 allegations in this paragraph of the Complaint.

16 72. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 73. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
24 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
25 paragraph of the Complaint.

26 74. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28 75. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or

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1 damage and deny the remaining allegations in this paragraph of the Complaint.

2 76. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 **Response to Second Cause of Action: Strict Liability**

5 77. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
6 Complaint as if fully set forth herein.

7 78. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Bextra®, and, therefore, deny the same. Defendants admit that Bextra® was expected to reach
10 consumers without substantial change in the condition from the time of sale. Defendants admit
11 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra®
12 in the United States to be prescribed by healthcare providers who are by law authorized to
13 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during
14 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,
15 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by
16 healthcare providers who are by law authorized to prescribe drugs in accordance with their
17 approval by the FDA. Defendants state that Bextra® was and is safe and effective when used
18 in accordance with its FDA-approved prescribing information. Defendants state that the
19 potential effects of Bextra® were and are adequately described in its FDA-approved prescribing
20 information, which was at all times adequate and comported with applicable standards of care
21 and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 79. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny the allegations in this paragraph of the Complaint.

27 80. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
4 allegations in this paragraph of the Complaint.

5 81. Defendants state that this paragraph of the Complaint contains legal contentions to
6 which no response is deemed required. To the extent a response is deemed required,
7 Defendants state that Bextra® was and is safe and effective when used in accordance with its
8 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
9 were and are adequately described in its FDA-approved prescribing information, which was at
10 all times adequate and comported with applicable standards of care and law. Defendants deny
11 that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph
12 of the Complaint, including all subparts.

13 82. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
18 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
19 Complaint.

20 83. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
25 allegations in this paragraph of the Complaint.

26 84. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
28 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Bextra® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants admit that, during certain periods of time,
5 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed
6 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
7 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
8 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
9 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
10 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
11 deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff
12 injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

13 85. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 86. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Bextra® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny the remaining allegations in this
25 paragraph of the Complaint.

26 87. Defendants state that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
28 deny the remaining allegations in this paragraph of the Complaint.

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1 88. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Bextra® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny that Bextra® is defective and deny the
8 remaining allegations in this paragraph of the Complaint.

9 89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
10 damage, and deny the remaining allegations in this paragraph of the Complaint.

11 90. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
12 damage, and deny the remaining allegations in this paragraph of the Complaint.

13 91. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Breach of Express Warranty

16 | 92. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
17 | Complaint as if fully set forth herein.

18 93. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Bextra® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants admit that they provided FDA-approved
25 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this
26 paragraph of the Complaint.

27 94. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

1 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Bextra® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants admit that they provided FDA-approved
6 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this
7 paragraph of the Complaint, including all subparts.

8 95. Defendants deny the allegations in this paragraph of the Complaint.

9 96. Defendants state that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Bextra® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants admit that they provided FDA-approved prescribing information regarding
14 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 97. Defendants state that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants admit that they provided FDA-approved prescribing information regarding
20 Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of
21 the Complaint.

22 98. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
24 Bextra®, and, therefore, deny the same. Defendants admit that they provided FDA-approved
25 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this
26 paragraph of the Complaint.

27 99. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

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1 100. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 101. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 **Response to Fourth Cause of Action: Breach of Implied Warranty**

6 102. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
7 Complaint as if fully set forth herein.

8 103. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
9 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
10 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
11 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
12 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
13 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
14 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
15 paragraph of the Complaint.

16 104. Defendants admit that they provided FDA-approved prescribing information regarding
17 Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that
18 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
19 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
20 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
21 prescribing information. Defendants deny the remaining allegations in this paragraph of the
22 Complaint.

23 105. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
25 the remaining allegations in this paragraph of the Complaint.

26 106. Defendants state that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and the remaining allegations in this paragraph of the
3 Complaint.

4 107. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Bextra®, and, therefore, deny the same. Defendants admit, as indicated in the package insert
7 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
8 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
9 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 108. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 deny the remaining allegations in this paragraph of the Complaint.

15 109. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
17 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was expected to reach
18 consumers without substantial change in the condition from the time of sale. Defendants deny
19 the remaining allegations in this paragraph of the Complaint.

20 110. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
25 Complaint.

26 111. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28 112. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or

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1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 113. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

5 114. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
6 Complaint as if fully set forth herein.

7 115. Defendants state that this paragraph of the Complaint contains legal contentions to
8 which no response is deemed required. To the extent a response is deemed required,
9 Defendants admit that they had duties as are imposed by law but deny having breached such
10 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Bextra® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny the remaining allegations in this paragraph of the Complaint.

15 116. Defendants state that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
20 the Complaint, including all subparts.

21 117. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 118. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
4 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

5 119. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 120. Defendants deny any wrongful conduct and deny the remaining allegations in this
12 paragraph of the Complaint.

13 121. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 122. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
19 Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
20 remaining allegations in this paragraph of the Complaint.

21 123. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
23 Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
24 remaining allegations in this paragraph of the Complaint.

25 124. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint.

27 125. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Bextra® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint.

7 126. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
8 damage, and deny the remaining allegations in this paragraph of the Complaint.

9 127. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
10 damage, and deny the remaining allegations in this paragraph of the Complaint.

11 128. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
12 damage, and deny the remaining allegations in this paragraph of the Complaint.

13 **Response to Sixth Cause of Action: Unjust Enrichment**

14 129. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
15 Complaint as if fully set forth herein.

16 130. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
17 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
18 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
19 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
20 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
21 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
22 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
23 paragraph of the Complaint.

24 131. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
26 Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this
27 paragraph of the Complaint.

28 132. Defendants are without knowledge or information sufficient to form a belief as to the

1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
2 Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this
3 paragraph of the Complaint.

4 133. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 deny the remaining allegations in this paragraph of the Complaint.

9 134. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
11 Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
12 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph
13 of the Complaint.

14 135. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 **Response to Prayer for Relief**

17 Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief,"
18 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
19 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

20 **III.**

21 **GENERAL DENIAL**

22 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's
23 Complaint that have not been previously admitted, denied, or explained.

24 **IV.**

25 **AFFIRMATIVE DEFENSES**

26 Defendants reserve the right to rely upon any of the following or additional defenses to
27 claims asserted by Plaintiff to the extent that such defenses are supported by information
28 developed through discovery or evidence at trial. Defendants affirmatively show that:

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First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

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Eighth Defense

2 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
3 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
4 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
5 liable in any way.

Ninth Defense

7 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
8 intervening causes for which Defendants cannot be liable.

Tenth Defense

10 10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were
11 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
12 of God.

Eleventh Defense

14 11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

16 12. A manufacturer has no duty to warn patients or the general public of any risk,
17 contraindication, or adverse effect associated with the use of a prescription medical product.
18 Rather, the law requires that all such warnings and appropriate information be given to the
19 prescribing physician and the medical profession, which act as a “learned intermediary” in
20 determining the use of the product. Bextra® is a prescription medical product, available only
21 on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s
22 treating and prescribing physicians.

Thirteenth Defense

24 13. The product at issue was not in a defective condition or unreasonably dangerous at the
25 time it left the control of the manufacturer or seller.

Fourteenth Defense

27 14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit
28 for its intended use and the warnings and instructions accompanying Bextra® at the time of the

occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or persons acting on its behalf after the product left the control of Defendants.

Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, the Constitution of the State of Michigan, and the Constitution of the State of California, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Michigan and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North*

¹ *America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

4 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
5 and marketing of Bextra®, if any, used in this case, included adequate warnings and
6 instructions with respect to the product's use in the package insert and other literature, and
7 conformed to the generally recognized, reasonably available, and reliable state of the
8 knowledge at the time the product was marketed.

Fortieth Defense

10 40. The claims asserted in the Complaint are barred because Bextra® was designed, tested,
11 manufactured and labeled in accordance with the state-of-the-art industry standards existing at
12 the time of the sale.

Forty-first Defense

14 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
15 and belief, such injuries and losses were caused by the actions of persons not having real or
16 apparent authority to take said actions on behalf of Defendants and over whom Defendants had
17 no control and for whom Defendants may not be held accountable.

Forty-second Defense

19 42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
20 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
21 intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

23 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,
24 waiver, and/or estoppel.

Forty-fourth Defense

26 44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the
27 pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or
28 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were

independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

21 50. Plaintiff's damages, if any, are barred or limited by the payments received from
22 collateral sources.

Fifty-first Defense

24 51. Defendants' liability, if any, can only be determined after the percentages of
25 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if
26 any, are determined. Defendants seek an adjudication of the percentage of fault of the
27 claimants and each and every other person whose fault could have contributed to the alleged
28 injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff’s claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff’s claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

1. The product in question was approved as safe and effective by the FDA and the labeling for said product was in compliance with FDA's approval at the time the products left the control of one or more Defendants and hence, Plaintiff's claims are barred by MCL 600.2946(5).

Fifty-ninth Defense

2. Plaintiff's claim for non-economic damages is capped pursuant to MCL 600.2946a.

Sixtieth Defense

3. To the extent Plaintiff proves that the products in question caused or contributed to any injury they may have suffered, which is denied by these Defendants, these Defendants should not be liable to warn as Plaintiff cannot prove that the scientific, technical or medical information that was reasonably available at the time was known or should have been known by the Defendants. MCL 600.2948.

Sixty-first Defense

4. Defendants assert all of the protections and defenses afforded them, and Plaintiff's claims of liability or damages are limited pursuant to the Michigan Products Liability Act including specifically, but not limited to MCL 600.2946 through MCL 600.6306, including MCL 600.2946, MCL 600.2946(a), MCL 600.2947, MCL 600.2948, MCL 600.2956, MCL 600.2957 and MCL 600.2959.

Sixty-second Defense

5. The product alleged to have caused damages may not have been used in the manner and for the purposes intended. Such improper use and/or abuse of the product for an unforeseeable purpose and in an unforeseeable manner may have proximately caused or contributed to the

1 alleged injuries, if any, and therefore there is no recovery available against Defendants pursuant
2 to MCL 600.2947.

Sixty-third Defense

4 6. Plaintiff's claim for non-economic damages is barred for the reason that Plaintiff's
5 percentage of comparative fault is greater than the aggregate fault of the Defendants and non-
6 parties hereto, pursuant to MCL 600.2959 and MCL 600.6306; but that to the extent allowable,
7 must be reduced in total or part pursuant to 600.2946(a).

Sixty-fourth Defense

9 7. The claims set forth in Plaintiff's Complaint are barred in that the product in question
10 was provided to a sophisticated user. In this case, the "user" would include any prescribing
11 physician.

Sixty-fifth Defense

13 8. Plaintiff failed to make every reasonable effort to mitigate, prevent and/or reduce their
14 alleged damages, injuries, and monetary losses.

Sixty-sixth Defense

16 9. Plaintiff's claims, part of Plaintiff's claims, or evidence relating to Plaintiff's claims
17 may be barred in whole or in part due to possible spoliation of evidence by Plaintiff, or those
18 within Plaintiff's control or with full knowledge of Plaintiff.

Sixty-seventh Defense

20 10. Any claims for punitive damages are barred in that they are not allowable under
21 Michigan law. To the extent that they are allowed contrary to Michigan law, such claims further
22 violate Defendants' constitutional rights under the following clauses of the United States
23 Constitution, as well as any similar provisions under the Michigan Constitution: Commerce
24 Clause, Contracts Clause, Supremacy Clause, Due Process, Takings Clause, Excessive Fines
25 and Equal Protection.

26 | 11.

Fifty-eighth Defense

28 12. Defendants reserve the right to supplement their assertion of defenses as they continue

with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

- 5 1. That Plaintiff take nothing from Defendants by reason of the Complaint;
 - 6 2. That the Complaint be dismissed;
 - 7 3. That Defendants be awarded their costs for this lawsuit;
 - 8 4. That the trier of fact determine what percentage of the combined fault or other liability
 - 9 of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries,
 - 10 losses or damages is attributable to each person;
 - 11 5. That any judgment for damages against Defendants in favor of Plaintiff be no greater
 - 12 than an amount which equals their proportionate share, if any, of the total fault or other liability
 - 13 which proximately caused Plaintiff's injuries and damages; and
 - 14 6. That Defendants have such other and further relief as the Court deems appropriate.

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1 January 17, 2008

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

January 17, 2008

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